UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

SUPERIOR HOME HEALTH SERVICES, L.L.C.,	
Plaintiff,	
v.	
	Case No: 5:15-cv-00636-RCL
ALEX M. AZAR II, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	
Defendant.	

MEMORANDUM OPINION

Before the Court is the Plaintiff's Amended Motion for Summary Judgment [ECF No. 31] by the plaintiff Superior Home Health Services, L.L.C., and the Defendant's Cross-Motion for Summary Judgment and Response to Plaintiff's Motion for Summary Judgment [ECF No. 35] by the defendant Alex M. Azar II,[1] Secretary of the United States Department of Health and Human Services, and all responses and replies thereto. For the reasons stated below, the Court: (1) **AFFIRMS** the Secretary's final administrative decision; (2) **DENIES** the plaintiff's Amended Motion for Summary Judgment [ECF No. 31]; and (3) **GRANTS** the defendant's Cross-Motion for Summary Judgment [ECF No. 35].

I. BACKGROUND

This case comes before the Court as an appeal from the final agency decision of the Departmental Appeals Board Medicare Appeals Council ("Council"), which determined that the

[1] Alex M. Azar II is the current Secretary of the U.S. Department of Health and Human Services. The caption has been updated accordingly.

plaintiff, Superior Home Health Services, L.L.C. ("Superior"), was overpaid by the Medicare program for home health services. ECF No. 1 at 3, ¶4.

Superior is a state-licensed, Medicare-certified home health care provider. *Id.* at 3-4, ¶5. On January 22, 2010, Superior was given the preliminary results of an audit conducted on its claims for coverage of home health services provided to beneficiaries between June 21, 2007, and April 10, 2009.[2] ECF No. 1-1 at 2 (the Council's final agency decision). Health Integrity, the Zone Program Integrity Contractor ("ZPIC") that conducted the initial audit, reviewed a 49-claim sample. *Id.* Twenty-six beneficiaries from this sample were determined to be ineligible for home health services pursuant to Medicare coverage criteria. *Id.* at 2-2.

The overpayment received by Superior was determined to be $70,825.17. ECF No. 1 at 8, ¶17. Health integrity then extrapolated the results of the sample to the universe of claims and determined the total overpayment to be $2,941,437.00. ECF No. 1-1 at 5. On March 30, 2010, the Medicare Administrative Contractor, Palmetto GBA, LLC ("Palmetto"), formally notified Superior of this overpayment. *Id.* Superior alleges that this formal notification did not include "any of the statistical data used to extrapolate the overpayment." ECF No. 1 at 8, ¶18.

Pursuant to the statutory appeal process,[3] Superior sought a redetermination by Palmetto. Palmetto reviewed each claim individually and ultimately upheld the overpayment determination, denying all claim appeals. ECF No. 1-1 at 5. On reconsideration, a Qualified Independent

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[2] It is not clear what the exact period of review was, as the various submissions to this Court by both parties contain differing dates (in some instances, the alleged date range differs within the same submitted document). Because the exact period of review does not matter for the purpose of this opinion, the Court will assume the relevant period stated in the Council's decision (ECF No. 1-1 at 2) is correct.

[3] Following an initial determination by a ZPIC that a claim does not meet the requirements for Medicare coverage, a beneficiary or provider may appeal the decision through a 5-step process: (1) redetermination by the Medicare administrative contractor (42 C.F.R. § 405.940 *et seq.*); (2) reconsideration by a qualified independent contractor ("QIC") (42 C.F.R. § 405.960 *et seq.*); (3) a hearing before an administrative law judge ("ALJ") (42 C.F.R. §§ 405.1002(a), 405.1006(b)); (4) review by the Medicare Appeals Council ("Council") (42 C.F.R. § 405.1100 *et seq.*); and (5) judicial review by a U.S. district court (42 U.S.C. § 1395ff(b)(1)(E); 42 C.F.R. § 405.1136; 42 C.F.R. § 405.1130).

Contractor ("QIC") upheld the overpayment as well, finding "the sampling methodology valid" and denying "the individual claims for coverage based on the appellant's failure to demonstrate the medical necessity of the various services." *Id.*

Superior contested the determination at an ALJ hearing on June 29-30, 2011. *Id.* During the hearing, Superior called expert witnesses challenging the ZPIC's sampling methodology, and presented testimony from a compliance expert and its former director of nursing addressing the coverage of the Medicare claims. *Id.* The ALJ determined that the sampling methodology was valid under applicable law, and that Superior was liable for the overpayment. *Id.* at 4. However, the Amended Decision issued by the ALJ on August 3, 2011, was partially favorable to Superior, finding that seven of the twenty-six claims in dispute had in fact satisfied Medicare coverage criteria, and that only nineteen of the forty-nine claims were deficient. ECF No. 35 at 7. These nineteen claims covered eighteen beneficiaries, as the sample included two separate claims for a single beneficiary. ECF No. 1-1 at 6 n.3.

At the final stage of administrative appeal prior to judicial review, Superior appealed the ALJ's findings to the Medicare Appeals Council. ECF No. 1-1 at 4. Superior asserted that the ALJ had made several errors of law regarding the sampling methodology, namely that the ZPIC had: (1) improperly reopened the claims; (2) proposed illegal recoupment of the alleged overpayment; and (3) violated the Medicare Benefit Policy Manual's "No Rule of Thumb" in its denial of coverage. *Id.* Superior asserted that the ALJ simply "lifted" the "same boilerplate language used by [the QIC]." *Id.* Lastly, Superior alleged errors of fact in (1) the ALJ's denial of coverage for the remaining eighteen beneficiaries, and (2) the ALJ's statistical analysis. *Id.*

The Council issued the Centers for Medicare & Medicaid Services ("CMS") final agency decision on June 3, 2015. *Id.* at 67. While partially reversing the ALJ in declaring the claims of

three of the remaining eighteen beneficiaries to be valid, the Council upheld the sampling methodology used to generate the extrapolated overpayment value. *Id.* It also affirmed Superior's liability for the remaining non-covered claims, and determined that Superior was ineligible for waiver of recoupment. *Id.* Finally, the Council ordered the extrapolated overpayment recalculated to reflect updated claim determinations. *Id.*

After exhausting all administrative remedies, Superior appeals the Council's decision to this Court for judicial review pursuant to 42 U.S.C. § 1395ff(b)(1)(A).

II. LEGAL STANDARD

A. Summary Judgment

Under Rule 56, summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). The moving party bears the burden of establishing the lack of a genuine issue of material fact. *Id.* If the movant does not bear the burden of proof at trial, he is entitled to summary judgment if he can point to an absence of evidence to support an essential element of the nonmoving party's case. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Similarly, a movant without the burden of proof at trial may be entitled to summary judgment if sufficient evidence "negates" an essential element. *Id.* The lack of proof as to an essential element renders all other facts immaterial. *Id.*

A fact is material if it could affect the outcome of the case. *Liberty Lobby*, 477 U.S. at 247. A dispute is genuine if the evidence is such that "a reasonable jury could return a verdict for the nonmoving party." *Id.* To survive summary judgment, a nonmoving party must present specific facts or evidence that would allow a reasonable factfinder to find in his favor on a material issue. *Id.* However, merely asserting a factual dispute or conclusory denials of the allegations raised by

the moving party is insufficient; the nonmoving party must come forward with competent evidence. *Id.* at 249-250. The nonmoving party may set forth specific facts by submitting affidavits or other evidence that demonstrates the existence of a genuine issue. *Id.*; *see also* Fed. R. Civ. P. 56(c). All inferences drawn from the facts must be viewed in the light most favorable to the non-moving party. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970). To prevail on a summary judgment motion there must be enough evidence on which a jury could reasonably find for the moving party. *Liberty Lobby*, 477 U.S. at 252.

B. Judicial Review

The parties argue for two different standards of judicial review. *Compare* ECF No. 31 at 6-7 *with* ECF No. 35 at 9-10. The Secretary contends that judicial review of the Council's final decision is governed by 42 U.S.C. § 405(g), which states in relevant part that a District Court of the United States:

> shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the case for a rehearing. The findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive . . . .

42 U.S.C. § 405(g). The Secretary further cites to Fifth Circuit precedent holding that where § 405(g) governs the standard of review, "appellate review is limited to two issues: (1) whether the Commissioner applied the proper legal standards; and (2) whether the Commissioner's decision is supported by substantial evidence on the record as a whole." *Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000). Because "Congress charged the Secretary with the primary responsibility for interpreting the cost reimbursement provisions of the Medicare Act," this Court is required to "accord particular deference to [the Secretary's] interpretation of Medicare legislation." *Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 215 (5th Cir. 1996). Substantial evidence is defined as

"more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)).

Superior argues that the standard of review is governed by the Administrative Procedure Act ("APA"), which "permits the setting aside of agency actions, findings, and conclusions that are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law' or 'unsupported by substantial evidence.'" *Cedar Lake Nursing Home v. U.S. Dep't of Health & Human Servs.*, 619 F.3d 453, 456 (5th Cir. 2010) (quoting 5 U.S.C. §§ 706(2)(A)-(E)). This standard is also generally deferential to administrative proceedings. *Id.*

In a similar dispute, also between a medical services provider and the CMS over alleged Medicare claim overpayments, the Fifth Circuit assumed "only for the sake of argument" that the arbitrary and capricious standard of the APA applied. *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335, 340 (5th Cir. 2017). "Because the standard of review 'probably makes no difference,' we make the same assumption here, too." *Id.* (quoting *Baylor Cty. Hosp. Dist. V. Price*, 850 F.3d 257, 261 (5th Cir. 2017)) (internal citations omitted). Also for the sake of argument, this Court will make the same assumption and apply the APA's arbitrary and capricious standard, as we agree that it "probably makes no difference."

III. DISCUSSION

A. The "Rule-of-Thumb"

Superior first argues that the sampling and extrapolation methodology used by the ZPIC violates what it calls the Medicare "Rule-of-Thumb." ECF No. 31 at 8. This "rule-of-thumb" is derived from language in the Medicare Benefit Policy Manual ("MBPM") which states that "[M]edicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs." MBPM,

Chap. 7, § 20.3. Because of this requirement that the claim of each beneficiary be individually evaluated on its own merits, Superior argues, "a 'rule-of-thumb' cannot be utilized to determine whether services are covered or not for hundreds or thousands of beneficiaries." ECF No. 31 at 8. Given this interpretation, Superior argues that the ZPIC's use of extrapolation to determine the total overpayment was error.

The Fifth Circuit has already rejected this exact argument, put forth by Superior's same attorney, in a prior case. *Maxmed Healthcare*, 860 F.3d at 343. Finding that the "rule-of-thumb" argument contradicts the CMS statutory scheme, the Fifth Circuit held, in relevant part:

> The Rule of Thumb makes sense for and applies to the prepayment review of individual coverage claims under Medicare. The MBPM provides guidance to Medicare contractors providing such prepayment review. What is appropriate when services are being authorized to Medicare beneficiaries, however, is not the standard for post-payment audits of providers. Congress authorized the Secretary's contractors to use extrapolation where, as in this case, "there is a sustained or high level of payment error." 42 U.S.C. § 1395ddd(f)(3)(A). This provision is part of the overall fiscal integrity program governing "[r]eview of activities of providers of services or other individuals or entities furnishing items and services for which payment may be made under this subchapter (including skilled nursing facilities *and home health agencies*)[.]" 42 U.S.C. § 1395ddd(b)(1) (emphasis added). Thus, Congress clearly envisioned extrapolation in overpayment determinations involving home health agencies . . . .

860 F.3d at 343. Given that this is settled law in the Fifth Circuit, the Secretary's use of extrapolation to determine the total value of the overpayment is justified, and is neither arbitrary nor capricious, nor unsupported by substantial evidence.

B. The Sampling and Extrapolation Methodologies

In its challenge to the Council's review of the ALJ's findings, Superior raises several points of error regarding the sampling and extrapolation methodologies employed by the ZPIC: (1) the Council exceeded its authority in "redrafting" the ALJ's findings [ECF No. 31 at 9]; (2) the Council failed to address Superior's challenge to the reliability of the sample [*Id.* at 10]; (3) the Council erred in concluding as a matter of law that substantial evidence in the record supported

the statistical sampling and extrapolation methodologies [*Id.* at 11]; and (4) the final agency decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and regulation. [*Id.* at 12]. The Secretary, in his cross-motion for summary judgment, refutes each of these alleged errors, calling for summary judgment in his favor. ECF No. 35 at 10-18.

1. The Council's review of the ALJ's findings

Superior asserts that the Council exceeded its authority by merely redrafting the findings of the ALJ and failing to address or even consider the testimony given by Superior's expert statisticians. ECF No. 31 at 9. Specifically, Superior points to testimony from "Dr. Cobb" at the ALJ hearing, who testified that "Health Integrity had failed to disclose all pertinent calculation documentation, that the claim lines were inconsistent, that undesirable claims were excluded from the universe which created substantial bias, and that the sample was not representative of the universe." *Id.* at 9-10. The Council, Superior argues, "cursorily declared" that the ZPIC's methodology met Medicare requirements, "affirming the validity of the calculations but supplanting the ALJ's findings with its own and the added benefit of a hind-sight review." *Id.* at 10. Superior asserts that the Council was "charged with determining whether the ALJ's decision was supported by substantial evidence in the record and premised upon correct legal principles." *Id.* at 9.

As the Secretary correctly points out in his cross-motion, the Council is in fact charged with reviewing the case *de novo*—not merely for substantial evidence and correct legal principles, as Superior asserts. *See* 42 U.S.C. §1395ff(d)(2)(B); *Maxmed Healthcare*, 860 F.3d at 338. Aside from vague, unsupported statements, Superior provides no basis for its claim that the Council merely redrafted the ALJ's findings instead of arriving at its own conclusions after properly considering the testimony and evidence before it. Moreover, Superior actually contradicts this very

assertion when it argues that the Council supplanted the ALJ's findings with its own with the "added benefit" of hindsight. *See* ECF No. 31 at 9-10. Surely the mere fact that the Council agreed with the ALJ's determination of validity regarding the sampling and extrapolation methodology does not demonstrate that it failed to do its own investigation into the facts of the case.

To the contrary, the Council thoroughly addressed the sampling guidelines set forth in the Medicare Program Integrity Manual ("MPIM") and the ZPIC's compliance with those guidelines in this case. ECF No. 1-1 at 8-21. Consequently, this Court finds that the Council's decision to uphold the ALJ's determinations regarding the validity of the sampling methodology was neither arbitrary nor capricious, nor unsupported by substantial evidence.

2. The Council's determination of sample reliability

Superior next argues that the sample selected by the ZPIC failed to comport with MPIM selection guidelines. ECF No. 31 at 10. The sampling universe defined by the ZPIC, Superior argues, was biased as a result of its exclusion of zero-payment claims and underpayments, the latter of which the MPIM states must be recorded as negative overpayments and included in the total overpayment value calculation. *Id.*; *see also* CMS Pub. 100-08 ("MPIM") § 8.4.5.2. Given this bias, Superior asserts that "the sample was not representative of the universe of claims" and that the projected extrapolation was therefore inaccurate. *Id.* at 11. Superior claims that its expert testified to this extent, stating that the sample was not representative of the universe by a factor of 5,010% and advocating for a different methodology that would have yielded a more accurate sample. *Id.*

The sampling universe selected by the ZPIC was "all claims from beneficiaries with 5 or more continuous full home care episodes and claims with payments greater than $1,000." ECF No.

1-1 at 17 (internal quotations omitted). Out of the 8,555 possible claims,[4] this filter narrowed the sampling universe down to 2,528 claims for which Superior was paid a total of $8,015,218.01 by the CMS. *Id.* Superior claims that this subset of claims was chosen in order to "deliberately exclude" zero payment claims and underpayments (what it refers to as "undesirable claims") in order to "cherry-pick[] the data for extrapolation." ECF No. 31 at 10-11. Superior supports this argument with language taken from the MPIM: "Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and *shall* also be used in calculating the estimated overpayment." MPIM § 8.4.5.2 (emphasis added).

As the Secretary points out and the Council's decision explains, there was in fact nothing arbitrary about the ZPIC's narrowing of the universe of claims. The ZPIC selected Superior for post-payment review because Superior was "the top provider in the State of Texas in terms of payment made for five or more continuous 60-day home health episodes (over $22 million) and 43% of its beneficiaries received five or more 60-day episodes." ECF 1-1 at 16. Moreover, the passage Superior quotes requiring that *sampling units* determined to be underpayments be included in overpayment calculations has nothing to do with defining the sampling universe. The language from section 8.4.5.2 merely states that sampling units (in this case, individual beneficiary claims) selected as part of the sample and later determined to be underpayments must be included as negative values in the calculation of the total overpayment. ECF No. 35 at 14; MPIM § 8.4.5.2. Here, none of the claims randomly selected for review were underpayments, and the passage is completely irrelevant to this case. ECF No. 1-1 at 18.

[4] Superior claims in its motion that the spreadsheet used by the ZPIC (titled "Sample HICNs Part B Claims) lists 8,555 total claims, out of which "381 were for amounts below $1.00, 1,355 were for amounts below $5.00, and almost 50% were for amounts below $20.00." ECF No. 31 at 10 n.3.

Superior cites to no additional authority beyond the testimony of its own expert witnesses that demonstrates the ZPIC erred as a matter of law by limiting the sampling universe as it did. To the contrary, the MPIM is clear that a ZPIC like Health Integrity has flexibility in choosing a sampling frame (i.e. "the 'listing' of all possible sampling units from which the sample is selected."). MPIM § 8.4.3.2.3. The sampling frame "may be, for example, a list of all beneficiaries receiving items from a selected supplier, [or] a list of all claims for which fully or partially favorable determinations have been issued." *Id.*

Superior's reading of section 8.4.5.2 of the MPIM is unconvincing. Given the large number of claims submitted by Superior for five or more continuous home health episodes, a trend that Superior does not dispute, it is unsurprising that the ZPIC sought to review a sample with the specifications it chose. Consequently, this Court does not find the Secretary's determination regarding the reliability of the sample to be arbitrary, capricious, or unsupported by substantial evidence.

3. The Council's determination that the sampling and extrapolation methodologies were valid

Superior attacks the general sampling and extrapolation methodologies used by the ZPIC to calculate the overpayment, arguing (1) that substantial evidence in the record does not support the method used, and (2) that the Council's decision that the methodologies were valid was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and regulation. ECF No. 31 at 11-12. It argues that the sample design was not "properly executed" as defined in section 8.4.2 of the MPIM, which states in relevant part:

> If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made.

MPIM § 8.4.2. "Based on expert testimony," Superior generally asserts that the ZPIC failed to follow MPIM procedures in its calculations, and therefore the presumption of validity afforded to its findings by the Council was unwarranted. ECF No. 31 at 12. Before addressing the merits of this argument, it is first necessary to briefly describe the guidelines for conducting statistical sampling and extrapolation, and where this presumption of validity comes from.

The Social Security Act states that extrapolation may not be used by a Medicare contractor to determine overpayment amounts unless the Secretary finds that (1) "there is a sustained or high level of payment error," or (2) "documented educational intervention has failed to correct the payment error." 42 U.S.C. § 1395ddd(f)(3).

The MPIM lays out the steps a contractor must follow when conducting statistical sampling:

> (1) Selecting the provider or supplier; (2) Selecting the period to be reviewed; (3) Defining the universe, the sampling unit, and the sampling frame; (4) Designing the sampling plan and selecting the sample; (5) Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable, (6) Estimating the overpayment.

MPIM § 8.4.1.3. When calculating the estimated overpayment, "the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier." *Id.* at § 8.4.5.1. As the Council explained in its decision, this effectively means that "there is a ninety percent chance that the actual overpayment is higher than the overpayment which is being assessed." ECF No. 1-1 at 10. Assessing the estimated value at this lower limit "incorporates the uncertainty inherent in the sample design" and "works to the financial advantage of the provider or supplier." MPIM § 8.4.5.1.

In order to ensure the validity of a sample, a Medicare contractor must use a methodology that results in a "probability sample." *Id.* at § 8.4.2. The MPIM defines a probability sample by two required features:

> - It must be possible, in principle, to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Although only one sample will be selected, each distinct sample of the set has a known probability of selection. It is not necessary to actually carry out the enumeration or calculate the probabilities, especially if the number of possible distinct samples is large – possibly billions. It is merely meant that one could, in theory, write down the samples, the sampling units contained therein, and the probabilities if one had unlimited time; and
>
> - Each sampling unit in each distinct possible sample must have a known probability of selection. For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.

Id. If a sample is "properly executed" such that a probability sample results, the extrapolated overpayment amount is entitled to a presumption of validity on review. *Id.*

The Council determined that the ZPIC followed all six required steps laid out in section 8.4.1.3 of the MPIM:

1. As discussed in the preceding subsection of this opinion, Superior was selected due to its status as "the top provider in the State of Texas in terms of payment made for five or more continuous 60-day home health episodes of care." ECF No. 1-1 at 16.
2. The period reviewed was June 21, 2007, to April 10, 2009. ECF No. 1-1 at 2.
3. "The sampling universe was 'all claims from beneficiaries with 5 or more continuous full home care episodes and claims with payments greater than $1,000 . . . There were 2,528 claims for which Superior . . . was paid a total of $8,015,218.01." *Id.* at 15. Each claim constituted a sampling unit, and the sample size was 49 claims. *Id.*

4. As to designing the sampling plan and selecting the sample, RAT-STATS software[5] was used to calculate the overpayment. "The sample-claims were randomly selected from the 2,528-claim universe, using a known seed number." *Id.*
5. The ZPIC reviewed the sample claims and determined that "26 out of 49 services were improperly reimbursed." *Id.* This constituted a 53% service error rate and an actual overpayment of $70,825.17. *Id.*
6. Using an 80% two-sided confidence interval, the ZPIC extrapolated a total overpayment of $2,941,337 with a 19.5% sample precision. *Id.* As the Council noted, and Superior has not disputed, "the lower bound of an 80% two-sided confidence level is equivalent to a one-sided 90% confidence level discussed in the MPIM." *Id.*

In its motion, Superior vaguely disputes that the sampling and extrapolation procedures actually resulted in a probability sample because the sample was not "properly executed." *See* ECF No. 31 at 12. It justifies this conclusion by pointing to expert testimony "outlined in section 2" of its motion, wherein it disputed the reliability of the sample due to the alleged bias resulting from the apparent exclusion of underpayments and zero-payment claims. *Id.* This argument, which is based entirely on an inaccurate reading of section 8.4.5.2 of the MPIM, has already been deemed meritless in the preceding subsection. It need not be addressed again here.

Superior lastly points to four cases filed by its same attorney in the U.S. District Court for the Southern District of Texas seeking judicial review of Medicare Appeals Council determinations regarding overpayments to medical care providers. ECF No. 31 at 13. It claims that in all four cases, the Medicare administrative contractor "rejected Health Integrity's statistical sampling and extrapolation." *Id.* Superior alleges that the contractor in each case used the "same

[5] The Secretary alleges, and Superior does not dispute, that "RAT-STATS is a widely used and accepted package of statistics software developed by the HHS Office of Inspector General."

methodology" employed by the ZPIC in this case, and that "a determination of whether or not the ZPIC's methodology is valid ought to be the same in every instance." *Id.* In *Maxmed Healthcare*, Superior's same attorney attempted to make the identical argument, alleging that "four recent cases filed in federal court in the Southern District of Texas demonstrate that Health Integrity's methodology was an arbitrary and capricious use and application of statistical sampling and extrapolation." *Maxmed Healthcare, Inc. v. Burwell*, No. SA:14-CV-988-DAE, 2016 WL 7486369, at *3 (W.D. Tex. Apr. 1, 2016). The Court held that "these complaints do not adequately inform the Court as to the parties' evidence, records, testimony, and statistical sampling, and whether they are exactly the same as those at issue in this case." *Id.*

Here, Superior cursorily cites to four cases that were voluntarily dismissed by the respective plaintiffs shortly after the complaints were filed. It provides no specific basis for this Court to conclude that the exact same methodology was in fact used in each case aside from conclusory assurances that this Court obviously cannot simply accept at face value. It cites no final agency decisions that may have been issued, nor any specific reasons why the sampling or extrapolation methodologies were rejected. The Court declines Superior's invitation to do its job for it by piecing together an argument out of separate, uncited administrative determinations regarding unique circumstances and evidence. This Court is tasked with reviewing the Secretary's final decision based on the record of this case alone, and Superior's attempt to incorporate mere allegations made in separate cases is unavailing.

Four reviewing entities have determined that the sampling and extrapolation methodologies employed by the ZPIC in this case resulted in a probability sample, and that the sample was therefore entitled to a presumption of validity. The Secretary has demonstrated with substantial evidence that the procedure used to extrapolate the overpayment value is compliant

with Medicare standards as set forth in 42 U.S.C. § 1395ddd and the MPIM. Superior has made clear in its submissions to this Court that its expert witnesses would have employed a different methodology, perhaps even one that would have yielded a significantly more accurate result—but it is not the function of this Court on judicial review to dictate which sampling and extrapolation methodologies must be used in administrative proceedings. What matters for the purpose of this appeal is the substantial evidence in the record supporting the Secretary's finding that the methodologies used by the ZPIC satisfied all relevant legal and administrative requirements. His decision pursuant to those findings was neither arbitrary nor capricious.

C. Medicare Coverage Determinations

Superior next argues that the Council erred by failing to consider substantial evidence in its favor as to Medicare coverage of each individual claim for home health services. ECF No. 31 at 15. It claims, specifically: (1) the Council rested its decision on the ZPIC's interviews "as opposed to the substantive evidence in favor of homebound status;" (2) the Council improperly applied "homebound" status rules; and (3) the Council improperly applied "medical necessity" rules. *Id.* at 15-19.

In order to qualify for home health services, a beneficiary must be: (a) confined to the home; (b) under the care of a physician who establishes a plan of care; (c) in need of skilled services; (d) under a qualifying plan of care that meets the requirements set forth in 42 C.F.R. § 409.43; and (e) receiving services from a participating home health agency. 42 C.F.R. § 409.42.

1. Interviews

Superior disputes the reliability of interviews taken by the ZPIC to determine homebound status at the time the home health services were rendered. *Id.* at 15. It asserts that the interviews were biased given that they were conducted between one and three years after services were

rendered, and because the interviewees were "persons with memory problems, dementia, and comorbidities of the ageing process." *Id.* Instead, it contends, "[c]ontemporaneous medical records prepared by registered nurses and home health professionals would logically stand as stronger, more reliable evidence, and should have been accepted not only by the ALJ but the Council." *Id.*

Superior points to no authority at all discounting the value of interviews in audit investigations of Medicare claims. Moreover, contrary to Superior's assertion that the ALJ and the Council "rested their decision" on the interviews, the Council's decision specifically states that it "employs a cautious approach when reviewing an audit agency's subsequent home health interview" due to "the inherent passage of time between an audit-based interview and service episode." ECF No. 1-1 at 39. This cautious approach was duly demonstrated when the Council found the interviews of four of the seven beneficiaries whose homebound statuses were in dispute to be unpersuasive or unreliable. *See id.* at 33 (finding interview record of Beneficiary M.C. unpersuasive to determine homebound status), 40 (finding interview record of Beneficiary I.G. insufficient to determine homebound status), 44 (finding interview record does not support the ALJ's finding that Beneficiary M.M. was not homebound), 46 (finding interview record of Beneficiary J.R. to be incomplete and insufficient to determine homebound status). The record contains substantial evidence that the Council did in fact assign the proper probative value to the interviews conducted by the ZPIC, and the Council's decision based on that information was neither arbitrary nor capricious.

2. Homebound Status

Superior moves for summary judgment on its assertion that the Council improperly denied homebound status to two beneficiaries (C.E. and M.M.(1)) by failing to apply relevant Medicare law. ECF No. 31 at 16. The statute reads in relevant part:

> an individual shall be considered "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home," the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

42 U.S.C. § 1395f(a). Furthermore, any "absence of an individual from the home shall not so disqualify an individual from being considered to be 'confined to his home.'" *Id.* Superior argues that in the case of each of the two disputed claims, the Council determined that neither beneficiary was homebound "because there was some evidence of their leaving the home during the 2-month period in question." ECF No. 31 at 16. In the case of Beneficiary M.M.(1), Superior asserts that the Council made this determination "because there were *three* noted absences from the home." *Id.* This determination was error, Superior argues, because certain infrequent activities that involve leaving the home are expressly allowed under the relevant statutes and the MBPM without disqualifying an individual from homebound status, including "tak[ing] walks around the block, go[ing] for drives," and going to church. *Id.* at 17. Indeed, the statute states that "any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration." § 1395f(a).

The record shows no indication that the Council was incapable of properly determining the homebound status of any beneficiary it considered. As the Secretary points out in his motion, the Council actually reversed the ALJ's determination that Beneficiary E.C.(1) was not homebound, finding his 5-day-per-week attendance at adult daycare, which was providing medical services, insufficient to destroy the beneficiary's homebound status. This determination was consistent with 42 U.S.C. § 1395f(a), which states that "[a]ny absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of

participating in therapeutic, psychosocial, or medical treatment in an adult day-care program . . . shall not disqualify an individual from being considered to be 'confined to his home.'"

Instead, the Council upheld the ALJ's decision that Beneficiary C.E. was not homebound due to: (1) the fact that the beneficiary was found to use a walker "at times," but was generally able to move about the home without the device; and (2) that the beneficiary recalled leaving the house every day to go shopping, out to eat, and to the grocery store, requiring assistance only in the form of a driver. ECF No. 1-1 at 38-39. Similarly, the Council cited the ZPIC's investigative findings that Beneficiary M.M.(1) was also determined able to leave the house frequently to go to "church, the grocery store, out to eat and medical care." *Id.* at 42. Like Beneficiary C.E., M.M.(1) only required the assistance of a driver. *Id.*

Superior's assertions that the Council failed to properly comport with Medicare requirements concerning the homebound statuses of the sampled beneficiaries are baseless. It is amply clear to this Court that the Council's findings were based on substantial evidence, and its determination based on that evidence was neither arbitrary nor capricious.

3. Medical Necessity of Skilled Services

Superior's final argument concerning the Council's allegedly improper determinations regarding Medicare coverage criteria asserts that the Council erred by finding a lack of medical necessity for skilled services in the cases of beneficiaries I.G., M.M.(3), J.R., J.A., E.C.(2), T.D.L.C., P.F., E.G., R.G., A.L., P.M., M.M.(2), and F.R. ECF No. 31 at 18. The Council denied these claims, Superior argues, "because the beneficiary was being instructed on 'mere' skills such as proper body mechanics/alignment, safe in-home mobility, and on the safe dosing and administration of insulin." *Id.* It alleges that the Council's decision was a function of its finding

that the "nursing visit notes were 'unremarkable' revealing no complaints or changes in condition." *Id.*

This, it contends, was an improper application of the law, as "Medicare statutes and regulations do not require significant changes in condition, medication, or treatment plan, or a decline in functional mobility for skilled nursing services to be considered reasonable and medically necessary." *Id.* at 18-19. Superior argues that its records demonstrated that the beneficiaries "were unable or unwilling to self-administer and/or could not be taught to self-administer insulin, even with the help of an auto-fill insulin pen." *Id.* at 19. It cites the MBPM, arguing that "'where the patient is either physically or mentally unable to self-inject and there is no other person who is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service.'" *Id.* at 19 (quoting MBPM, Ch. 7, § 40.1.2.4).

42 C.F.R. § 409.32 defines "skilled services" for the purpose of determining Medicare coverage, as well as the requirements to receive Medicare-covered skilled services. A skilled service is an activity "so inherently complex that it can be safely or effectively performed only by, or under the supervision of, professional or technical personnel." 42 C.F.R. § 409.32(a). In cases where a beneficiary has special medical complications, "a service that is usually nonskilled . . . may be considered skilled because it must be performed or supervised by skilled nursing or rehabilitation personnel." *Id.* at § 409.32(b).

42 C.F.R. § 409.33 lists services that could qualify as skilled nursing services, including (1) overall management and evaluation of care plans, (2) observation and assessment of the patient's changing condition, and (3) education services to teach the patient self-maintenance. *See* § 409.33(a). Overall patient management qualifies "when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in

order to meet the patient's needs, promote recovery, and ensure medical safety." § 409.33(a)(1)(i). Additionally, patient observation and assessment may qualify "when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition is stabilized." § 409.33(a)(2)(i). Patient education services are necessary in the skilled nursing context "if the use of technical or professional personnel is necessary to teach a patient self-maintenance." § 409.33(a)(3)(i).

However, "[i]f the nature of a service is such that it can safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse, the service cannot be regarded as a skilled nursing service." § 409.44(b)(1)(ii). Services may be considered reasonable and necessary when they are "consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice." § 409.44(b)(3)(i).

Superior cites no specific errors in the Council's determinations of medical necessity of skilled services as to any individual beneficiary, instead generally asserting that "[t]he Council failed to apply the clear and proper Medicare 'medical necessity' standards for payment." ECF No. 31 at 19. The Court will briefly address the Council's determinations as to each beneficiary whose status is herein disputed:

i. Beneficiary I.G.

Based on the skilled nursing notes, the Council found that the services provided to Beneficiary I.G. were largely limited to: (1) lifestyle instruction; (2) safe in-home mobility; and (3) treatment of diabetes. ECF No. 1-1 at 40. Visit reports were "unremarkable revealing no significant complaints or changes in the beneficiary's condition," with "no likelihood of change in

the beneficiary's condition which required skilled nursing personnel to identify and evaluate the beneficiary's need for modification of treatment." *Id.* at 41. None of the activities performed were deemed so inherently complex that a medical professional was required. *Id.*

ii. Beneficiary M.M.(3)

The Council found that skilled nursing services provided to M.M.(3) consisted primarily of: (1) assessment and observation of the patient; and (2) instruction on disease treatment. *Id.* at 43. The instruction provided concerned teaching the patient and her caregivers about "diabetes, hypertension and pain management," as well as "diet, safety, fall prevention and medication management." *Id.* at 44. The Council found that: (1) none of these services were sufficiently complex that a medical professional was required to administer them; (2) the record demonstrated no likelihood of change in condition requiring skilled services to modify treatment; and (3) the teaching was unskilled and repetitive. *Id.* at 45.

iii. Beneficiary J.R.

The Council found that services provided were largely limited to: (1) patient observation and assessment of various disease elements; and (2) glucometer testing when the patient and/or caregiver were unable to do so themselves. *Id.* After reviewing the relevant documentation, the Council found that "[t]he beneficiary was largely independent in terms of blood glucose testing and insulin administration," and that patient's medical history during the relevant period was "otherwise stable and unremarkable." *Id.* at 47. The Council determined that: (1) the record demonstrated no likelihood of change in condition requiring skilled nursing services; (2) the services rendered were not sufficiently complex; and (3) the instruction provided was unskilled and repetitive. *Id.*

iv. Beneficiary J.A.

After identifying that the ALJ's findings included an incorrect factual account, the Council determined, based on the relevant evidence, that the skilled nursing services provided to Beneficiary J.A. were largely limited to: (1) performing assessments of all body systems; (2) providing disease-related care instruction related to diabetes and pain management; and (3) conducting glucometer testing. *Id.* at 48. The beneficiary's condition was "largely unremarkable" during the period of service, with blood glucose levels remaining within parameters in the plan of care. *Id.* "Identified medication 'instruction' was limited to general admonitions to take prescribed, unexpired, medications only and as only directed." *Id.* at 48-49. Consequently, the Council determined that: (1) the record indicated no likelihood of a change in condition requiring skilled nursing personnel to identify and oversee treatment modification; (2) the instruction was unskilled and repetitive; and (3) the services provided were not sufficiently complex to require a medical professional. *Id.* at 49.

v. Beneficiary E.C.(2)

Based on witness testimony and the relevant medical record, the Council found that services provided to Beneficiary E.C.(2) were largely limited to: (1) observation and assessment of body systems; (2) monitoring of vital signs; and (3) instruction on "elements of safe mobility within the home and the manner in which to take medication, predominantly Coumadin." *Id.* at 49-50. As the MBPM specifies, "[t]he administration of oral medications by a nurse is not reasonable and necessary skilled nursing care except in the specific situation in which the complexity of the patient's condition, the nature of the drugs prescribed, and the number of drugs prescribed require the skills of a licensed nurse to detect and evaluate side effects or reactions." *Id.* at 50 (quoting MBPM, Ch. 7, § 40.1.2.4). The Council determined that: (1) the instruction was "little more . . . involvement than to relay instruction to the beneficiary;" (2) the record indicated

that the treatment was not sufficiently complex to require medical professionals; and (3) instruction was unskilled and repetitive. *Id.*

vi. Beneficiary T.D.L.C.

Based on witness testimony and the relevant medical record, the Council determined that the services provided to Beneficiary T.D.L.C. were limited to: (1) assessment and observation of all body systems; (2) monitoring vital signs; (3) monitoring glucose levels; and (4) instruction on "pain, diet, urinary incontinence energy conservations and the processes of various medical conditions." *Id.* at 51. The Council noted that "[t]he evidence reveals that the skilled nurse's predominant role was monitoring the beneficiary's medical condition and providing instruction on various areas of self-care, diet and medication management." *Id.* at 52. The Council found that: (1) the services provided were insufficiently complex to qualify as skilled services; (2) the record indicated no likelihood of changes in condition requiring skilled nursing services; and (3) the instruction was unskilled and repetitive. *Id.*

vii. Beneficiary P.F.

Based on witness testimony and the relevant medical record, the Council determined that the services provided to Beneficiary P.F. were largely limited to: (1) assessment and observation of all body systems; (2) monitoring vital signs; and (3) providing instruction on disease processes. *Id.* at 53. It found that education services "consisted of instruction relative to aspects of disease progress and management, diet, general safety concerns and relaxation techniques." *Id.* The Council determined that: (1) the services provided were insufficiently complex to qualify as skilled services; and (2) the record indicated no likelihood of changes in condition requiring skilled nursing services.

viii. Beneficiary E.G.

Based on witness testimony and the relevant medical record, the Council found that the services provided to Beneficiary E.G. were largely limited to: (1) assessment of the beneficiary's body systems; and (2) instruction regarding elements of self-care and medication management (including wound care). *Id.* at 55. "New medications identified in the plan of care consisted of an oral medication for cramps and a hand cream." *Id.* The Council determined that: (1) the services provided were insufficiently complex to qualify as skilled services; (2) the record indicated no likelihood of changes in condition requiring skilled nursing services; and (3) the instruction was unskilled and repetitive. *Id.*

ix. Beneficiary R.G.

Based on witness testimony and the relevant medical record, the Council found that the services provided to Beneficiary R.G. were largely limited to: (1) assessment and observation of all body systems; (2) monitoring of vital signs; and (3) instruction on glucose monitoring. *Id.* at 56. It found that "the skilled nurses' predominant role were [sic] to monitor the beneficiary's medical condition, assess vital signs, provide instruction in areas of self-care, diet, medication management [sic] as well as to ensure that the beneficiary, recently widowed, was aware of the community's various social, emotional, financial and psychological resources available to assist with that personal transition and make appropriate referrals." *Id.* The Council determined that: (1) the services provided were insufficiently complex to qualify as skilled services; (2) the record indicated no likelihood of changes in condition requiring skilled nursing services; and (3) the instruction on glucose monitoring was unskilled and repetitive. *Id.* at 57.

x. Beneficiary A.L.

Based on witness testimony and the relevant medical record, the Council found that the services provided to Beneficiary A.L. were largely limited to: (1) observation and assessment of

all body systems; (2) preparation and administration of insulin; and (3) instruction on diabetes management, the administration of new medications, hypertension, and pain management. *Id.* at 59. It found that "[t]he evidence indicates that the skilled nurse expended significant time in what was essentially routine monitoring and repetitive instruction." *Id.* at 60. The Council determined that: (1) the services provided were insufficiently complex to qualify as skilled services; (2) the record indicated no likelihood of changes in condition requiring skilled nursing services; and (3) Superior "did not identify the newly introduced 'medication' prescribed just prior to this period of service or otherwise indicate that skilled nursing services were required for its administration." *Id.*

xi. Beneficiary P.M.

Based on witness testimony and the relevant medical record, the Council found that the services provided to Beneficiary P.M. were largely limited to: (1) assessment and observation of all body systems; (2) blood glucose testing; and (3) instruction on diabetes, congestive heart failure, hypertension and benign prostatic hypertrophy. *Id.* at 61. It found that the beneficiary "was capable of self-monitoring blood glucose and his residence was free of safety concerns," and that the nurse predominantly "provided general instruction on disease management." *Id.* The Council consequently determined that: (1) the services provided were insufficiently complex to qualify as skilled services; and (2) the record indicated no likelihood of changes in condition requiring skilled nursing services. *Id.* at 61-62.

xii. Beneficiary M.M.(2)

Based on witness testimony and the relevant medical record, the Council found that the services provided to Beneficiary M.M.(2) were largely limited to: (1) assessment and observation of all body systems; (2) monitoring of vital signs; (3) blood glucose testing; and (4) instruction on atrial fibrillation, diabetes and hypertension management. *Id.* at 62. It found that "the beneficiary's

medical history was largely stable" during the period of service, and that "the nursing services included clearing pathways for mobility, providing instruction on various aspects of disease and diet management, as well as physical energy saving techniques." *Id.* at 63. The Council determined that: (1) the services provided were insufficiently complex to qualify as skilled services; (2) the record indicated no likelihood of changes in condition requiring skilled nursing services; and (3) the instruction was unskilled and repetitive. *Id.*

xiii. Beneficiary F.R.

Based on witness testimony and the relevant medical record, the Council found that the services provided to Beneficiary F.R. were largely limited to: (1) assessment and observation of all body systems; (2) monitoring of vital signs; and (3) instruction on hypertension and arthropathy. *Id.* at 64. It found that "the reports associated with the skilled nursing visits in issue are largely unremarkable revealing no significant complaints or changes in the beneficiary's condition." *Id.* Consequently, the Council determined that: (1) the services provided were insufficiently complex to qualify as skilled services; (2) the record indicated no likelihood of changes in condition requiring skilled nursing services; and (3) the instruction was unskilled and repetitive. *Id.*

4. Conclusion: Medical Necessity

Based on the above summarizations of the Council's findings and determinations as to each individual beneficiary whose claims are currently in dispute, the Court finds that the Secretary has supported his findings with substantial evidence. While Superior identifies the "exact medical bases for each beneficiary that justified home health nursing services" in its reply brief, it fails to carry its burden of showing that the Secretary's determinations were arbitrary or capricious in any way. *See* ECF No. 37 at 6-8.

D. Alleged Due Process Violations

Superior moves for summary judgment on the basis that the Secretary violated its due process rights on two grounds: (1) by withholding critical evidence from December 9, 2010, when Superior requested the ALJ hearing, until the day of the ALJ hearing; and (2) by failing to comply with statutory deadlines for adjudicating appeals, resulting in an egregious delay. ECF No. 31 at 19, 21. After an action arising under the Medicare Act has been "channeled" through all levels of the administrative process, a district court on judicial review has authority to resolve "any statutory or constitutional contention that the agency does not, or cannot, decide." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 23 (2000). The instant action has been channeled through all four levels of administrative appeal, and this Court has authority to decide Superior's due process claim. *See Maxmed Healthcare*, 152 F. Supp. 3d at 640.

1. Withholding of Evidence

Superior contends that Health Integrity "only disclosed evidence on the sampling and extrapolation methodology to Superior after the reconsideration decision was issued, and disclosed more upon instruction from the ALJ prior at the hearing in 2014." *Id.* at 19-20. The Council found that no such due process violations had occurred, as the evidence was in fact provided prior to the ALJ hearing. *Id.* at 20. Superior contends that the Council erred in this determination, as it "should have received an opportunity to challenge the overpayment at redetermination and reconsideration, *before* the ALJ hearing took place." *Id.* It claims it was entitled to review of the extrapolation methodology used by the ZPIC at each of the first two stages of appeal. *Id.* Because "Medicare guidelines require CMS contractors to disclose information about the review and statistical sampling that was followed to calculate an overpayment," it argues, its due process rights were violated when such information was not disclosed prior to the first stage of appeal. *Id.* (citing 405 C.F.R. § 405.371; 42 U.S.C. § 1395ddd(f)(3)). The "absence from the administrative record" of

this information "is grounds for invalidating an extrapolation." *Id.* at 21 (citing *Chaves County Home Health Svcs., Inc. v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991)).

Just as the Fifth Circuit stated in response to a similar due process claim in *Maxmed Healthcare*, "[w]e are unaware of any authority holding that agency processes become fundamentally unfair under the circumstances before us." 860 F.3d at 344. Superior never contends in any submission to this Court that it ever even requested the information on the sampling and extrapolation methodologies from the ZPIC, and it cites no relevant authority mandating that such information be disclosed prior to either the redetermination or reconsideration stages in a Medicare administrative appeal. *See* ECF No. 31 at 19-21; ECF No. 37 at 10-11. It is undisputed that the information on sampling and extrapolation methodologies was in fact provided to Superior prior to the ALJ hearing, and the information was therefore not absent from the administrative record. *Compare* ECF No. 31 at 20 *with* ECF No. 35 at 31. Superior has consequently "failed to produce sufficient evidence to survive summary judgment that it was deprived of 'notice and opportunity for hearing appropriate to the nature of the case,' which is the hallmark of a due process claim." *Maxmed Healthcare*, 152 F. Supp. 3d at 640 (quoting *Mullane v. Cent. Hanover Bank & Tr.*, 339 U.S. 306, 313 (1950)). The first ground of Superior's due process claim is therefore rejected.

2. Failure to Comply with Statutory Deadlines

Superior's second ground for its due process claim states that the Secretary's failure to comply with the statutory deadlines for adjudicating its Medicare appeals constituted such an egregious delay as to deny Superior its constitutional right of due process. ECF No. 31 at 21. As set forth in the Medicare Act, an ALJ is required to conduct and conclude a hearing and render a decision within 90 days of a Medicare provider's request following reconsideration by a QIC. 42 U.S.C. §§ 1395ff(d)(1)(A). Likewise, the Medicare Appeals Council is required to conduct and

conclude a review of the ALJ's decision and either make its own decision or remand the case to the ALJ within 90 days of the provider's request for review. § 1395(d)(2)(A). That the Secretary failed to fully comply with the statutory deadlines in Superior's administrative appeal is undisputed in this case. *See* ECF No. 31 at 21-22; ECF No. 38 at 9.

The Court sympathizes with Superior's frustration in the significant delays now essentially guaranteed by the decision to appeal an initial Medicare claim overpayment determination. Crippling backlog in the administrative process is a recognized issue throughout the country, as demonstrated by the continuing litigation pursued by the American Hospital Association. *See Am. Hosp. Ass'n v. Price*, 867 F.3d 160, 162-165 (D.C. Cir. 2017). Unfortunately for Superior and the many other affected providers nationwide, Congress has explicitly provided a remedy for failure to meet each of the deadlines in question. If an ALJ fails to render a decision by the end of the 90-day statutory period, the appellant may bypass the ALJ stage of appeal and request a review by the Council. 42 U.S.C. § 1395ff(d)(3)(A). If the Council fails to meet its 90-day deadline after a request for review of an ALJ decision is filed, an appellant "may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review." § 1395ff(d)(3)(B).

That these remedies have been explicitly spelled out in the Medicare Act indicates that Congress anticipated delays yet declined to set for further remedy than that provided in the statute. *See Cumberland Cnty Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 55 (4th Cir. 2016) ("In giving the healthcare provider these options, Congress anticipated that the 90–day deadline might not be met and provided its chosen remedy."). Further remedies beyond the statutory text must come from Congress. The second ground of Superior's due process claim must therefore be rejected as well.

E. Limitation on Liability

Finally, Superior argues, in the event the Council's overpayment determinations are upheld, it should be relieved of liability pursuant to 42 U.S.C. § 1395pp. It asserts that its liability should be waived given that it "did not know, and could not reasonably have been expected to know, that payment would not be made" for its home health services, as allowed by the statute in such circumstances. 42 U.S.C. § 1395pp(a)(2).

A provider like Superior may be held liable for the cost of denied services deemed not to be "reasonable and necessary" as defined under 42 C.F.R. § 411.15(k). Constructive notice of noncoverage may be imposed on a provider based on:

> (1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives . . . .
>
> (2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.
>
> (3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

42 C.F.R. 411.406(e). The Council found that the beneficiaries were not liable for the non-covered claims, as "[t]here is no evidence that the beneficiaries knew, or could have reasonably been expected to know, that their home health services would not be covered." ECF No. 1-1 at 65. However, it found that Superior, as a provider of Medicare-covered services, "knew or should have known that Medicare would not cover these charges based on knowledge of Medicare coverage criteria." *Id.*

42 U.S.C. § 1395 allows for a waiver of liability to be issued if the provider was "without fault with respect to the payment of such excess over the correct amount." § 1395(b)(1). A provider is "without fault" if it "exercised reasonable care in billing for, and accepting, the payment." Medicare Financial Management Manual (MFMM), CMS Pub. 100-06, Ch. 3, § 90. Conversely, the provider is *not* without fault if it should have known that the services provided were not covered

by Medicare. *Id.* at 90.1.H. The Council determined that Superior, as a provider with both actual and constructive knowledge of Medicare coverage regulations, was not without fault in the overpayments.

As discussed already, judicial review of a final administrative decision is generally deferential to the agency's findings. The Court concludes that substantial evidence, including Superior's status as a Medicare-certified provider, supports the Council's determination that Superior should have known that the services it provided would not be covered by Medicare, and that the Secretary's decision to impose liability for the overpayments on Superior was neither arbitrary nor capricious.

IV. CONCLUSION

For all the reasons stated above, the Court: (1) **AFFIRMS** the Secretary's final administrative decision; (2) **DENIES** the Plaintiff's Amended Motion for Summary Judgment [ECF No. 31]; and (3) **GRANTS** the Defendant's Cross-Motion for Summary Judgment [ECF No. 35].

A separate order shall issue this date.

Date: August 3, 2018

Royce C. Lamberth
United States District Judge